



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: May 03, 2021

SUBJECT: Efficacy Review for Envirocleanse A
EPA Reg. No. 85134-1
DP Barcode: 461046
E-submission No. 59657

FROM: Md Mizanur Rahman
Risk Assessment Branch 2
New Chemicals Division, OPPT

THRU: Thao Pham
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: May 25, 2021

TO: Demson Fuller, PM 32/ Daniel Halpert
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: Envirocleanse, LLC.,
22762 Westheimer Pkwy, Suite 515,
Katy, TX 77450

Mizanur Rahman

Thao Pham

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Hypochlorous Acid.....	0.025%
<u>Other Ingredients</u>	99.975%
Total.....	100.000%

I BACKGROUND

Product Description (as packaged, as applied): Ready-To-Use disinfectant

Submission type: (A570) Label amendment requiring data review

Currently registered efficacy claim(s): Hospital, health clinics, doctors' offices, dental offices, nursing homes, veterinary facilities, homes, restaurants and other facilities; broad spectrum disinfectant (bactericidal, and virucidal activity) for use on hard, non-porous surfaces.

Requested action(s): Label amendment to add virucidal efficacy claims against SARS-CoV-2 (the cause of COVID-19).

Documents considered in this review:

- Cover letter from applicant to EPA dated 01/25/2021
- Proposed label dated 01/25/2021
- Data Matrix (EPA Form 8570-35) dated 01/25/2021
- One efficacy study (MRID 51440901) (amended 4/7/21)
- Confidential Statement of Formula (EPA Form 8670-4) dated 06/25/2009

II PROPOSED DIRECTIONS FOR USE

Disinfection of Hard, Non-porous Surfaces

(Envirocleanse-A) (This product) can be used to disinfect hard, non-porous surfaces. To disinfect, apply (Envirocleanse-A) (this product) to any hard, non-porous surface with a cloth, mop, sponge or coarse sprayer. Wet the surfaces thoroughly and allow surface to remain wet for 10 minutes. Allow treated surface to air dry. Remove visible soil from surfaces before applying this product. Small non-porous objects can also be soaked in Envirocleanse-A without dilution. Allow objects to soak for 10 minutes.

Veterinary / Animal Facilities Applications

To clean and disinfect in a veterinary application: Use to clean and disinfect hard, nonporous surfaces such as feeding and watering equipment, cages, utensils, instruments, kennels, stables, catteries, etc. Remove all animals and feed from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings, and manure from walls, floors, and surfaces or facilities occupied or traversed by animals. Empty all feeding and watering equipment. Remove gross filth from surfaces before applying this product. Saturate surfaces with (Envirocleanse-A) (this product) and let stand for 10 minutes. Thoroughly scrub all treating, feeding, and watering appliances with soap or detergent, and rinse with potable water before reuse. Disinfection of animal quarters and kennels: To clean and disinfect hard nonporous surfaces, remove all animals and feed from premises. Remove all litter, droppings, and manure from floors, walls, and surfaces of facilities occupied or traversed by animals. Remove gross filth from surfaces before applying this product. Saturate surfaces with (Envirocleanse-A) (this product) for a period of 10 minutes. Immerse handling and restraining equipment such as leashes, muzzles, halters, and ropes. Allow equipment and housing to completely dry after use and before returning animals.

Agricultural Applications

For livestock or poultry facilities or dairy barns, remove all animals and feed from the premises, vehicles, coops, crates, and enclosures. Remove all litter, manure, and droppings from the floors, walls, and surfaces of barns, pens, chutes, and other facilities occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Remove gross filth. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with (Envirocleanse-A) (this product) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Rinse with potable water before reuse. For cut flowers or plants, dilute (Envirocleanse-A) (this product) with water by 1:25 ratio to spray on the flowers or plants, and put in the vase to mitigate and retard the growth of non-public health microorganisms affecting the health and longevity of the flowers or plants. Repeat and change water if it gets murky.

III STUDY SUMMARIES

1.	MRID	51440901
Study Objective		Disinfectant-Virucidal against SARS-COV-2
Testing Lab; Lab Study ID		Analytical Lab Group-Midwest; A31676
Experimental Start Date		01/05/2021
Study Completion Date:		01/19/2021
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		SARS-Related Coronavirus 2, BEI Resources NR-52281, Strain Isolate USA-WA1/2020
Indicator Cell Culture		Vero E6 cells; Source: ATCC CRL-1586
Test Method		ASTM E1053-20
Application Method		Three sprays from the spray bottles was applied to the test carriers from a distance of 6-8 inches and held covered for the exposure time.
Test Substance Preparation	Name/ID	Envirocleanse, EPA Reg. No. 85134-1
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	11/30/20 1, 11/30/20 2, 11/30/20 3
	Preparation	Tested concentration: LCL Tested Dilution: Diluted to LCL (330 ppm FAC equivalent to about 231ppm HOCl) Diluent: Sterile deionized water (used to minimally dilute to LCL)
Soil load		5.0% Fetal Bovine Serum (FBS)
Carrier type, # per lot		100x15 mm sterile glass Petri dishes
Test conditions		Contact time: 1 minute Temperature: 19.25°C Relative humidity: 20.61%
Neutralizer		Sephadex LH-20 gel
Reviewer comments (i.e., protocol deviations and amendments, retesting, control failures, etc.)		Report amended April 7, 2021. This protocol is amended to clarify the ppm range specified on page 9 of the protocol, in the Product Preparation section, is For Free Available Chlorine (FAC). The ppm of the dilutions tested are in FAC. Protocol Deviations: No protocol deviations occurred during this study.

IV STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results			Dried Virus Control (Log ₁₀ TCID ₅₀ /carrier)
			Lot 11/30/20 1	Lot 11/30/20 2	Lot 11/30/20 3	
Envirocleanse applied as a spray for 1 min contact time (5% fetal bovine soil)						
51440901	Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-Related Coronavirus 2), BEI Resources NR-52281, Strain Isolate USA-WA1/2020	10 ⁻¹ to 10 ⁻⁶ dilution*	Complete inactivation	Complete inactivation	Complete inactivation	5.80
		Log ₁₀ TCID ₅₀ /carrier	≤ 0.80	≤ 0.80	≤ 0.80	
		Log Reduction	≥ 5.00	≥ 5.00	≥ 5.00	

*Dilution refers to the fold of dilution from the virus inoculum. Post neutralized sample was considered the 10⁻¹ dilution.

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support label claims?
51440901	Disinfectant, virucidal	Hard non-porous surface	RTU spray	1 min	5% fetal bovine serum	Sterile deionized water (used to minimally dilute to LCL)	Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-Related Coronavirus 2), BEI Resources NR-52281, Strain Isolate USA-WA1/2020	Yes

VI LABEL COMMENTS

Label Date/Identification Number: 01/25/2021/ Envirocleanse, EPA Reg. No. 85134-1

1. The proposed label claims that the product, Envirocleanse, when applied as a ready to use spray, is an effective disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 1-minute contact time:

Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) (Strain USA-WA1/2020, Source: BEI Resources NR-52281)

This claim is **acceptable** as it is supported by the submitted data.

2. Make the following changes to the proposed label:

- i. Throughout the label,
 - a. Each instance of claims against SARS-CoV-2 should clearly indicate for treatment of “hard nonporous surfaces”.
 - b. All elimination claims should be qualified with the appropriate percent reduction as the data do not demonstrate complete elimination of the challenge organisms. Qualify each instance of “ (Eliminates)” or similar on hard, non-porous surfaces with 99.9% as the standalone claim may imply complete kill.
 - c. Revise “all around the house” and similar claims to specify for use on environmental surfaces. This is to not mislead users to use the product in areas other than environmental surfaces.
 - d. Qualify one-step claims with “when used according to disinfection directions.”
 - e. Qualify “multi-surface” with “hard nonporous”.
 - f. Ensure each instance of germ, germs, germicide, or germicidal is qualified per the agency’s guidance from germ claims: <https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels>.
 - g. Remove “2019 Novel Coronavirus” or specify “formerly”. The virus has been officially classified as SARS CoV 2.
- ii. On page 2-4,
 - a. Replace the words ‘remain wet’ with ‘remain visibly wet’; ‘thoroughly wet’ with ‘visibly wet’
 - b. Revise “gross filth” to “visible soil”
- iii. On pages 5 and 20 of the label, remove parentheses from “exterior” as this is not optional. In addition, surfaces such as stove tops and ovens should specify “allow surfaces to come to room temperature prior to treatment.”
- iv. On page 7 and 9, remove “fast” claims or clarify these to specify sanitizing activity as these claims are typically limited to contact times of 30 seconds or less.
- v. On page 9, remove “protect like the pros” as this implies residual efficacy.
- vi. On page 13, remove or revise “spread of illness-causing (kitchen) bacteria” to “reduces cross contamination of bacteria between treated surfaces”

- vii. On page 15, remove “eliminator” and “takes care of” as this is misleading and implies complete kill. Alternatively, qualify with 99.9%.

Note to PM: Please review “gentle” or “mild”; potential implied safety claims. In addition, please review “electronically activated” for accuracy.